

REMARKS

At the outset, applicants wish to point out that the Office Action dated November 20, 2003 was incorrectly mailed to the wrong law firm. A revocation and substitution of power of attorney was filed on August 27, 2003. Applicants received a return postcard from the USPTO which acknowledged receipt of this paper (copy enclosed). Applicants request that the USPTO ensure that the new power of attorney is recorded, and that the USPTO records be corrected to reflect the correct mailing address for papers related to this application.

The November 20, 2003 Official Action and references cited therein have been carefully reviewed. In light of the amendments presented herewith, and the following remarks, favorable reconsideration and allowance of the application are respectfully requested.

At page 2 of the Official Action, the Examiner has maintained the rejection of claims 4, 5, 16, 17, 31-34, 36-38, 65, 67, and 68 under 35 U.S.C. §112, first paragraph, asserting that the specification does not reasonably provide the enablement necessary to practice the full scope of the claims.

At page 4 of the Official Action, the Examiner has rejected claims 4, 5, 16, 17, 30-38 and 65-68 under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

The foregoing constitutes the entirety of the rejections raised in the November 20, 2003 Official Action. In light of the present claim amendments and the following remarks, each of the above-noted rejections under 35 U.S.C. § 112, first and second paragraph are respectfully traversed.

Support for the amendments to claim 1 can be found in original claim 34, and in the specification at page 19, line 8.

The features which are added to claim 1 are components of the original claim, were explicitly disclosed in the specification, and therefore do not contain new matter.

**CLAIMS 4, 5, 16, 17, 31-34, 36-38, 65, 67, AND 68 AS AMENDED ARE
FULLY ENABLED BY THE SPECIFICATION AS FILED**

The Examiner has maintained the rejection of claims 4, 5, 16, 17, 31-34, 36-38, 65, 67, and 68 under 35 U.S.C. §112, first paragraph. In general, it is the Examiner's position that it would require undue experimentation for one skilled in the art to practice the full scope of the invention.

The Examiner does indicate at page 2 of the Official Action, that claims to the treatment of reentrant atrial flutter using plasmid based vectors are enabled.

Applicants respectfully submit that the claims are enabled.

As set forth in the previous office action, at pages 11-12 of the specification as originally filed, the HERG gene is described, as is the HERG gene A561V mutation. This mutation is known and disclosed to produce a defective potassium channel rectifier, which interferes with the WT HERG potassium channel rectifier in a dominant negative manner. Expression of A516V HERG mutant in cardiomyocytes inhibits K⁺ current through the HERG membrane protein, and delays myocardial conduction. This is the same mechanism by which ibutilide, an art standard treatment for re-entrant arrhythmias acts. Thus the instant specification discloses the explicit mechanism of cardiac re-entrant arrhythmias, and provides a treatment which acts by the same mechanism as the art known treatment.

The specification also provides guidance for alternative means of treating re-entrant atrial flutter, and for treatment of other disorders, using reverse gene therapy. For example, at pages 13-14, alternate reverse gene therapy targets for treating

re-entrant atrial flutter are disclosed. At pages 16-18 guidance for selecting and utilizing other specific genes for reverse gene therapy treatment of specific corresponding disorders are discussed.

Furthermore, contrary to the Examiner's assertion, any reverse gene therapy vector would work in the methods of the invention. Numerous types of vectors which are efficacious for delivery of nucleic acid are known in the art. Additionally, exemplary reverse gene therapy vectors are described in the specification at page 19. Accordingly, it would not require undue experimentation to use different types of reverse gene therapy vectors to deliver genetic material to the cells of the invention, as vectors for delivery of genetic material were known in the art and described in the specification.

In summary, the specification provides extensive guidance to the skilled person, and a description of the underlying disease mechanism, for the treatment of cardiac arrhythmias, as well as other disorders. Further, many different gene delivery vectors are known in the art and described in the specification. In light of all the foregoing, it cannot be reasonably maintained that undue experimentation would be required to practice the invention as claimed.

Nonetheless, in the interest of expediting prosecution, applicants have amended the claims to recite a method for treating re-entry atrial flutter using a plasmid-based reverse gene therapy vector. As mentioned previously, the Examiner has indicated that the specification fully enables such a method.

In light of the foregoing claim amendments, and remarks, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

**CLAIMS 4, 5, 16, 17, 31-34, 36-38, 65, 67, AND 68 AS AMENDED
FULLY COMPLY WITH 35 U.S.C. 112 SECOND PARAGRAPH**

The Examiner has rejected claims 4, 5, 16, 17, 30-38 and 65-68 under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

The Examiner indicates that the recitation of "the cardiac cell", in claim 4 allegedly lacks antecedent basis. Accordingly, the claim has been amended to provide proper basis for this phrase. It is respectfully submitted that this amendment renders the rejection under 35 U.S.C. §112, second paragraph, moot.

CONCLUSION


It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the amendments and remarks presented herein, it is respectfully urged that the rejections set forth in the November 20, 2003 Official Action be withdrawn and that this application be passed to issue. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned

attorney at the phone number given below.

Respectfully submitted,
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